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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/542,406

03/29/2006

Bernadette Verneau

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FOLEY AND LARDNER LLP  
SUITE 500  
3000 K STREET NW  
WASHINGTON, DC 20007

EXAMINER

MI, QIUWEN

ART UNIT

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/542,406	<b>Applicant(s)</b> VERNEAU, BERNADETTE	
	<b>Examiner</b> QIUWEN MI	<b>Art Unit</b> 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1, 14-23 and 26-34 is/are pending in the application.
- 4a) Of the above claim(s) 15, 16, 23 and 26-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 14, 17-22, 33 and 34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/13/08</u> .  | 6) <input type="checkbox"/> Other: _____                          |

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### **DETAILED ACTION**

Applicant's amendment in the reply filed on 11/13/08 is acknowledged, with the cancellation of Claims 2-13, 24, and 25. Claims 1, and 14-23, and 26-34 are pending. Claims 15, 16, 23, and 26-32 are withdrawn as they are directed toward a non-elected invention groups or species. **Claims 1, 14, 17-22, 33, and 34 are examined on the merits.**

Any rejection that is not reiterated is hereby withdrawn.

### **Claim Rejections –35 USC § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 14, 17-22, 33, and 34 remain rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Mann (US 5,273,754), Mamana (US 2002/0192308), and Hosoya et al (JP 2001064672 A).

This rejection is maintained for reasons of record set forth in the Office Action mailed out on 8/14/2008, repeated below. Applicants' arguments filed have been fully considered but they are not deemed to be persuasive.

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Mann teaches an appetite suppressant composition leading to a decrease in weight (col 1, lines 5-10) comprising a heating carminative substance, such as standard oleoresin capsicum which contains capsaicin (thus capsaicinoids) (thus in the form of capsicum resin) (col 2, lines 45-50), and a cooling carminative substance selected from peppermint, menthol, and spearmint etc (thus contains a vegetable oil) (claim 3; example 2). Mann also teaches that capsaicin is a preferred heating carminative substance, ...having a gastric heating effect exhibits a local anesthetic effect in the stomach (particularly upon the gastric nerves controlling hunger) when administered orally at a sufficient dose (col 2, lines 30-40). Mann further teaches that the appetite suppressant composition in a form suitable for oral administration, and preferably as a capsule (thus solid or pasty at room temperature) (col 4, lines 22-28).

Mann does not teach the incorporation of soya oil, and green tea into the composition, and neither does Mann teaches the claimed amount of the components.

Mamana teaches an appetite suppressant for controlling weight comprising green tea or green tea leaf extract (thus one or more physiologically active components) (claim 1). Mamana also teaches a method of controlling weight by replacing at least one meal with a soy based meal replacement (claim 22) (thus contains soya oil, a vegetable oil). Mamana further teaches that the appetite suppressant is preferably administered orally in the form of a capsule etc (thus solid or pasty at room temperature) [0014].

Hosoya et al teach a fat metabolizer ingested (thus acceptable for oral administration) in very small amount comprising fats and oils consisting of diglyceride and/or monoglyceride,

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triglyceride (thus a lipophilic additive, solid or pasty at room temperature), linseed oil (thus a vegetable oil) etc. Hosoya et al also teach that the obtained fats and oils filled in a soft capsule (thus solid or pasty at room temperature). Hosoya et al teach that the results obtained showed that BMI, body fat rate and waist size were efficiently reduced without changing the eating habits of the persons (see Abstract, full translation has been ordered).

"It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose ...[T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted).

In the instant case, all of the above-listed ingredients were known for weight control. Thus, one of ordinary skill in the art would have had a reasonable expectation that the combination of these compounds would have been additively beneficial in weight control.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit since each is well known in the art for weight control. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, In re Sussman, 1943 C.D. 518.

It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 220 F2d 454,456,105 USPQ 233; 235 (CCPA 1955). see MPEP § 2144.05 part II A. Although the prior art did not specifically disclose the amounts of each constituent as in the claims, it would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal concentrations of components because concentration is an art-recognized result-effective variable which would have been routinely determined and optimized in the pharmaceutical art.

Accordingly, the instant claims, in the range of proportions where no unexpected results are observed, would have been obvious to one of ordinary skill having the above cited references before him.

Therefore, it would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to combine the inventions of Mann, Mamana, and Hosoya et al since all of them teach compositions for weight control individually in the art. Since all the compositions yielded beneficial results in weight control, one of ordinary skill in the art would have been motivated to make the modifications. Regarding the limitation to the amount of the components in the composition, the result-effective adjustment in conventional working parameters is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan, which is dependent on the body weight, age, and appetite of the patient that is needed.

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From the teachings of the references, it is apparent that one of the ordinary skills in the art would have had a reasonable expectation of success in producing the claimed invention.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Applicant argues that “Surprisingly, Applicant has discovered that the incorporation of a formulation base containing both a vegetable and/or mineral oil and a lipophilic additive which is solid or pasty at room temperature results in a composition which lacks any irritant effect on the gastric mucosa (see the *in vivo* test on page 11). The specification discloses the results of "Digestive Tolerance Tests on Healthy Subjects" demonstrating that the invention provides a surprising improvement in the reaction of human subjects to capsicum (page 11, line 9, et seq.). Accordingly, even if a *prima facie* case of obviousness were properly made out, which Applicant denies as explained below, such a *prima facie* case would be effectively rebutted by the unexpected results disclosed in the present specification” (page 7, last three paragraphs).

This is not found persuasive. According to MPEP 716.02 (a), a greater than additive effect is not necessarily sufficient to overcome a *prima facie* case of obviousness because such an effect can either be expected or unexpected. Applicants must further show that the results were greater than those which would have been expected from the prior art to an unobvious extent, and that the results are of a significant, practical advantage. *Ex parte* The NutraSweet Co., 19 USPQ2d 1586 (Bd. Pat. App. & Inter. 1991). In the instant case, Applicant needs to present a side by side comparison between the claimed invention and the closest art to show the

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allegedly surprising results, mere argument or allegation is insufficient to overcome the obviousness rejection.

Applicant argues that “The Office has combined the three documents Mann, Mamana, and Hosoya by improper hindsight consideration of the invention. Applicant respectfully observes that, even if a man skilled in the art had the idea to look in documents dealing with body weight control, the probability for him to choose the three quoted documents was very faint. As a matter of fact, there are thousands of molecules known to have an effect on weight control. To illustrate this point, Applicant submits the review article of Pittler et al (Am J Clin Nutr 2004; 79: 529-36) and the botanical draft list of Article 13 Health Claims of the European Commission (both documents filed concurrently herewith in an Information Disclosure Statement), showing that, for natural botanical compounds only, more than 20 compounds were known for decades to influence body weight” (page 8, 1-3 paragraphs). Applicant argues that “The Office has not indicated what would lead a person ordinarily skilled in the art who wants to realize a composition which stimulates thermogenesis so as to, potentially, control body weight, to choose specifically the three cited documents Mann, Mamana, and Hosoya. Applicant faithfully considers that it was none: nothing in the cited documents triggers the man skilled in the art to combine these documents among others (page 8, 4<sup>th</sup> -5<sup>th</sup> paragraphs).

In response to Appellant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so



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long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the Appellant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

In addition, the basis for the 103 resides in the knowledge that each individually claimed component was already known in the art for weight control and that one of ordinary skill in the art, having the above-cited references before him or her would have recognized the advantageous nature of combining the ingredients in order to achieve an additive effect on weight control.

Applicant argues that "Mann teaches "an undesirable burning sensation sometimes results upon the ingestion of the heating carminative substance" (column 3, lines 31-33). However, Mann does not teach how to alleviate this burning sensation. Also, neither Mamana nor Hosaya, which disclose respectively an appetite suppressant composition and a weight reducing composition, teach how to counteract the gastric burning effect of the capsaicinoids (page 8, 2<sup>nd</sup> paragraph from the bottom).

Applicant argues that "Mann teaches an appetite suppressant composition leading to a decrease in weight, comprising at least i) a heating carminative substance, and ii) a cooling carminative substance. In a preferred embodiment, said heating carminative substance is capsaicin. Mann teaches that the heating carminative substance is "a substance having a gastric heating effect and exhibits a local anaesthetic effect in the stomach (particularly upon the gastric nerves controlling hunger) (column 2, lines 30-33)". However, "an undesirable burning sensation sometimes results upon the ingestion of the heating carminative substance" (column 3, lines 31-33)" (page 9, last paragraph bridging page 10).

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Applicant argues that “Thus, it was known that heating carminative substances such as capsaicin were efficient to decrease weight, but were also associated with pain and irritation in the gastric mucosa” (page 10, 2<sup>nd</sup> paragraph).

Applicant argues that “For a person of ordinary skill in the art seeking to realize an appetite suppressant composition containing capsaicinoids as active principle for regulating weight, the problem was to find a way to bypass these painful symptoms” (page 10, 3<sup>rd</sup> paragraph).

Applicant argues that “Moreover, neither Mamana nor Hosaya, which disclose respectively an appetite suppressant composition and a weight reducing composition, teach to counteract the gastric burning effect of the capsaicinoids by the use of formulation base containing a vegetable oil and/or mineral oil and a lipophilic additive” (page 10, 5<sup>th</sup> paragraph).

This is not found persuasive. Mann teaches using cooling carminative substance to diminish any undersirable burning sensation caused by using capsicum (col 3, lines 30-35).

Applicant argues that “As a matter of fact, there is no link between the three documents:

- Mann teaches an appetite suppressant composition leading to a decrease in weight, comprising at least i) a heating carminative substance, and ii) a cooling carminative substance. Mann does not refer to lipophilic additives or oils.
- Mamana discloses an appetite suppressant composition comprising green tea or green tea leaf extracts. Also, Mamana teaches a method of controlling weight by replacing at least one meal with soy based meal. Mamana is silent concerning capsaicinoids, or lipophilic additive or oils.

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- Hosoya teaches a fat metabolizer ingested in very small amount comprising fats and oils, which is actually a mixture of specific proportions of mono-, di-, and tri-glycerides whose fatty acids moieties are obtained from vegetable (linseed, sesame and rapeseed) or fish oils. As these fatty acids are unsaturated, resulting mono-, di-, and tri-glycerides are ~ at room temperature, and are therefore not pasty or solid at room temperature. Thus, Hosoya does not disclose any lipophilic additive which is pasty or solid at room temperature. Moreover, Hosoya is silent concerning capsaicinoids

Hence, the only way to choose these three references for combination was to choose them starting from the invention. Such reasoning is erroneously based on hindsight reconstruction of the invention. Therefore, considering all the published prior art documents, a person of ordinary skill in the art would not have combined the three documents” (page 8, last paragraph; page 9, 2<sup>nd</sup> -3<sup>rd</sup> paragraphs).

This is not persuasive. First of all, all the references teach compositions for weight control, thus, one of ordinary skill in the art would have had a reasonable expectation that the combination of these compounds would have been additively beneficial in weight control. Secondly, in response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

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Applicant argues that "Even if Mann, Mamana, and Hosoya were combined, the result would not yield the present invention, because these documents fail to disclose or suggest the use of a "lipophilic additive which is solid or pasty at room temperature" as recited in claim 1.

"All words in a claim must be considered in judging the patentability of that claim against the prior art." M.P.E.P. 2143.03, quoting *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970) (page 9, 2<sup>nd</sup>-3<sup>rd</sup> paragraphs from the bottom).

Applicant argues that "Mann does not teach to add any formulation base containing a vegetable oil and/or mineral oil and a "lipophilic additive which is solid or pasty at room temperature" as presently claimed. Instead, Mann only discloses adding either "cooling carminative substances" (e.g., peppermint, menthol, spearmint, carvone or mixture thereof), amino acids (e.g., L-methionine, D-phenylalanine, glycine or mixtures thereof), and/or anxiolytic substances (e.g., valerian, damiana, chamomile, kava, passion flower, hops, skullcap, St John's Wort, extracts thereof or mixtures thereof)" (page 10, 4<sup>th</sup> paragraph).

Applicant argues that "None of these documents teach the use of a lipophilic additive which is solid or pasty at room temperature in their composition" (page 10, 2<sup>nd</sup> paragraph from the bottom).

Applicant argues that "As a matter of fact, and contrary to what the Office alleged, Hosoya does not disclosed lipophilic additive which are solid or pasty at room temperature: monoglycerides, diglycerides and triglycerides isolated by transesterification from vegetable and fish oils are indeed at room temperature, depending on their fusion temperature and length of saturated chain" (page 10, last paragraph).

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Applicant argues that “In contract, in the present invention the exemplified glycerides are those whose fatty acid moiety consists of palmitic and stearic acid, which are saturated fatty acids, and therefore are pasty or solid at room temperature” (page 11, 3<sup>rd</sup> paragraph).

Applicant argues that “Applicant has here shown that:

- Mann, Mamana, and Hosoya fail to disclose lipophilic additives which are solid or pasty at room temperature, and
- Mann, Mamana, and Hosoya fail to disclose the advantageous anti-burning effects of lipophilic additive that are solid or pasty at room temperature.

It was thus not obvious for the man skilled in the art to associate a formulation base containing a lipophilic additive which is solid or pasty at room temperature with a capsaicinoid in order to attenuate the capsaicinoid's gastric burning effect” (page 11, 3<sup>rd</sup>-6<sup>th</sup> paragraphs).

Applicant argues that “Moreover, as none of these documents teach the use of lipophilic additive which is solid or pasty at room temperature in their composition, a person of ordinary skill in the art, who had by pure chance combined the teaching of Mann, Mamana, and Hosoya would not have realized the present invention” (page 11, last paragraph).

This is not found persuasive. Since Hosoya et al teach a fat metabolizer comprising fats and oils consisting of the claimed lipophilic additive diglyceride and/or monoglyceride, triglyceride, thus it is deemed that those components have the claim designated properties, which is solid or pasty at room temperature, regardless whether the cited reference explicitly teaches that or not.

Applicant's arguments have been fully considered but they are not persuasive, and therefore the rejection in the record the maintained.

### **Conclusion**

No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Qiuwen Mi whose telephone number is 571-272-5984. The examiner can normally be reached on 8 to 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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QM

/Michael V. Meller/

Primary Examiner, Art Unit 1655